

SPL Process ER/DL Meeting

Meeting Minutes

May 20, 2015

Chair of today's meeting: Pat Cowall-Hanover

Teleconference information:

USA Toll-Free 866-213-2145

USA Paid/International: 609-454-9913

Access code: 273 8216

Teleconference information: How to mute/unmute

#6: Mute

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Link to the SPL wiki:

<http://spl-work-group.wikispaces.com/share/view/51351516>

Agenda:

1. NCPDP rules for product identifiers (Tricia Pasek)

Has anyone heard of the NCPDP (National Council for Prescription Drug Programs) Product Identifiers Standard, Implementation Guide, Version 1.0 (10/2014)?

I would like to specifically point out **Page 7, 4-4-j**

4. RULES FOR NCPDP PRODUCT IDENTIFIERS

4. A new identifier will be assigned if any of the following characteristics of the product/package change:
 - a. Product name change
 - b. Active ingredient change including use of a different salt
 - c. Package size change
 - d. Significant product or packaging change such that patients and/or healthcare professionals:
 - i. will be confused by using the same identifier, or
 - ii. the patient may experience an adverse or allergic reaction
 - e. Physical appearance change (color, shape, imprint, scoring, etc.)
 - f. Dosage form change
 - g. Federal Legend Product (Rx)/Over The Counter (OTC) status change
 - h. Strength change
 - i. Package component change (addition/deletion of swabs, cotton balls, etc. or anything that will cause a change in the billing unit)
 - j. Inclusion or removal of promotional free goods (i.e. 10 free antihistamine tablets with cold symptom relief liquid)

I took this ONLY for promotional free goods when referencing 2 completely different products as in the example; **free tablet product with purchase of a liquid product**. However, we had a request from a customer, that for Medicaid/Medicare purposes, we assign a new NDC size code for the following situation:

- Regular Packaging - 40 tablets in 1 bottle, NDC xxxxx-xxx-12 (40 count)
- Promotional Packaging – 40 tablets in 1 bottle – 30 tablets + 10 free, NDC xxxxx-xxx-34 (40 count)

How are other companies handling this?

Responses before the meeting:

Howard: If the promotional package is being priced less than the 40-count bottle then I think a separate NDC is appropriate. From an SPL validation standpoint you can use a separate package code for the promotional bottle even though the package type and quantity in the package are the same and from the perspective of highlighted item -- it is a separate package, the regular package is a 40-count bottle and the other is a 30-count bottle with an additional 10 tablets at no extra charge.

- Mary Beth: It's the NDC that is included in insurance claims/CMS etc for billing. There is an 11-digit version of NDC specifically for the purposes of billing. So if you use the same NDC, then you'll get reimbursed for 1 price – so the 10 free tablets wouldn't really be free.
- Question forwarded to Lonnie. NO response as yet.
- Meeting discussion:
- NDC should change with each different label/package. Therefore 30 plus 10 should be a separate package.....from either the 30 or 40 package.
- Include only 1 PDP image for the label of the product, but have separate NDC numbers.
- The products will have different descriptions in your price list and with reimbursement agencies.
- Will share feedback from Lonnie.

2. Question on timing for de-listing – are people still using last lot expiry as marketing end date? (Ann Prindle).

See the following from the March 25, 2015 meeting minutes.

- Many companies are using last lot expiry for a market end date.
- Process:
 - Step 1: Put in the market end date
 - Step 2: Remove the product from the SPL at a convenient time. It is helpful to leave in for at least a year, since CMS may reimburse for up to a year after last lot expiry.
- The NSDE is a cumulative file. Expired products remain in the NSDE directory.
- Are both CDER and CBER accepting data down to the pack level.
 - Pack level only works for CDER products.
 - Validation rule 3.1.8.14, page 49 or 50 of the IG.

I have two questions for you:

- Is the withdrawal from sale date the same as marketing end date?

Meeting discussion:

No. The date should be the expiration of the last lot – this is the last possible day that this product can be legally sold in the market.

3. Impact of changing the Labeler codes and NDC numbers for Commercial products with an acquisition. Discuss pros and cons. (Elaine Ogunbiyi and Dawn)

Meeting discussion:

- If you are acquiring a whole company, then you have the option of changing the NDCs or not
- If you decide to do this, then you have to add the new ones, and then add a market end date to the “old” NDC code – date should be after the last lot has expired.
- Divested a product: If they were taking the old product, did transfer letters, delisted the old product. New product listed with their own product.
- Need to have coverage for the old products. Don’t delist until after the expiration of the product. Need to work with the reimbursement group so that patients are reimbursed.
- Note: if you change over to new NDC codes, you will have a new SPL – and you will have to update both labels if you have a safety labeling change.

4. DUNS information: For companies that don’t have specific support people identified, what ways are you using to get DUNS information and/or get help in changing the information.
- iUpdate: But....this D&B website says you must be an executive officer of the company.
 - Susanne Correia, Merck – provided the following link that was given to her. It validates data for the purpose of drug listing. If the DUNS data fails validation, the message tells you what is failing, why it fails, and the email contact of the D&B representative in that country.

<https://fdadunsvalidation.com/login.aspx>

Reminder:

Lot Distribution Reporting: Electronic submission of Lot Distribution Reports becomes effective June 10, 2015.

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM412006.pdf>